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Impact of Missing Data on Analysis of Postoperative Cognitive Decline (POCD)

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Abstract

Background—There are a variety of techniques to handle missing data, such as removing observations with missing data from the analyses or estimating the missing values using various imputation algorithms. Dropping subjects from standard regression models and analyzing only completers, however, may bias results from the true value of reality. Likewise, 'last-observation-carried-forward' may not be an appropriate technique for studies measuring a particular variable over time.

Methods—This dataset was part of a larger prospective cohort study that examined Postoperative Cognitive Decline (POCD) after surgery in older adults. Data collectors had provided the reasons for data being missing using adjectives including 'confused,' 'incapable,' 'stuporous,' 'comatose,' and 'intubated.' Data having these qualitative notations were re-coded as 'incapable' and trial scores of zero were recorded. This value of '0' indicated that the patient was cognitively incapable of performing the neuropsychological test.

Results—Missing data varied by cognitive test and postoperative day. Re-coding Word List scores from missing to zero when a patient was too cognitively impaired to complete the tests improved sample size by 13.5% of Postoperative Day (POD) 1 and 12.8% on POD 2. Recoding missing data to zero for the Digit Symbol test resulted in 29.3% larger sample size on POD 1 and

22.7% on POD 2. Verbal Fluency gained 15.7% sample size with re-coding for POD 1 and 13.7% for POD 2. Re-coding of each cognitive test reduced missing data sample size to 20–32% in all cognitive tests for each day.

Discussion—Our data suggest that using a scoring system that enters a value of '0' when patients are unable to perform cognitive testing did significantly increase the number of patients that met the diagnosis of postoperative cognitive decline using the criteria that were determined a priori and may lessen chances of Type II error (failure to detect a difference).

Keywords

cognition; missing data; methods

Missing data are a problem in human research, particularly in health related studies in which many factors can potentially alter response rates. Statistical methods for handling missing data typically assume that causes of missing data are 'independent' of the dependent variable, termed 'missing at random' (DeSouza, Legedza, & Sankoh, 2009). There are a variety of techniques to handle missing data, such as removing the observations with missing data from the analyses or estimating the missing values using various imputation algorithms. Missing data, for example, are often dropped from standard regression models, analyzing only 'completers' which may bias results from the true value of reality (Wittes, 2009). Likewise, 'last-observation-carried-forward' may not be an appropriate technique for studies measuring a particular variable over time.

Most statistical methods for handling missing data assume that data are 'missing at random', an assumption that is often incorrect in health-related research. One of the more popular techniques is Multiple Imputation, which generates multiple possible alternatives for each missing value, analyzes each dataset, and then combines the results in a way that reflects the variability between models (Abayomi, Gelman, & Levy, 2005). These analytic techniques are based upon the assumption that data are 'missing at random', which may increase the risk for bias and lower the reliable interpretation of trial results (Fleming, 2011). Since missing data in longitudinal health-related research is a common occurrence, a call for viable strategies that improve accuracy of conclusions is needed. These strategies need to include methods that can more adequately distinguish between 'missing' or 'dropout' data versus a true change in the variable of interest (Kenward & Molenberghs, 2009).

Research related to cognitive status is at particular risk for missing data. Use of repeated measures of cognitive status is an important component of accurate and timely diagnosis. While procedures should be in place to reduce missing data at scheduled time points, conditions often occur which reduce data capture. Studies of postoperative cognitive decline (POCD), for example, are likely to encounter difficulties in collecting cognitive status data. Postoperative cognitive decline (POCD) consists of problems with cognition after surgery including such areas as memory, executive functioning, and speed to processing (Tsai, Sands, Leung, 2010). POCD is distinguished from delirium or dementia but is not currently recognized in the International Classification of Diseases (ICD) nor the Diagnostic and Statistical Manual (DSM). Typically POCD refers to whether a patient's cognitive performance is significantly lower than the preoperative level of performance in one or more neuropsychological domains. Baseline and follow-up cognitive data are needed to determine presence of POCD. Missing preoperative or postoperative cognitive data are likely to occur for a variety of reasons including disruptions by medical personnel (e.g. for patient assessment or therapy), equipment (e.g. intubated), or patient unresponsiveness. The purpose of this study, therefore, was to examine the occurrence of missing cognitive data in the postoperative setting and to perform further analyses using methods to limit potential bias that may occur with standard imputation methods. The aims of this study are to:

1. Determine incidence of missing postoperative data;
2. Compare rates of postoperative cognitive decline (POCD) excluding missing data versus including re-coded data in analysis;
3. Identify relevant characteristics associated with having partial postoperative information

Study Design

This dataset was part of a larger prospective cohort study that examined POCD after surgery in older adults. The larger study was conducted from 2001–2007 at a large academic medical center with a sample of adults aged 65 and older who were undergoing non-cardiac surgery. Institutional Review Board (IRB) approval was obtained prior to data collection.

Participants were introduced to the study at the time of their preoperative anesthesia and surgical preparation visit. Enrolled subjects underwent a baseline evaluation of cognitive status in a quiet, private room close to the preoperative clinic. Cognitive status was reassessed at approximately 24 and 48 hours after surgery at the patients' bedside postoperatively. Data were collected by research assistants trained by one of the authors (LS). Every attempt was made to collect data at similar time points while coordinating postoperative care.

Variables

Baseline cognitive status was assessed with the Telephone Interview for Cognitive Status (TICS). TICS is an instrument adapted from the Mini Mental State Examination (MMSE) that can be administered either face-to-face or by telephone (Desmond, Tatemichi, & Hanzawa, 1994). Compared with the MMSE the TICS has a sensitivity of 1.00 and a specificity of 0.83. A cutoff score of less than 25 indicates dementia. Clinical information was obtained from participants' medical records. Surgical risk is based upon the American College of Cardiology and the American Heart Association guidelines which consider the type of surgery, duration of surgery, and blood loss. Three categories exist and are identified in our study as '0' being 'low risk', '1' being 'intermediate risk', and '2' being 'high risk' (ACC/AHA, 2002). Charts were reviewed for a history of central nervous system (CNS) disorders such as cerebrovascular accident (CVA), dementia, delirium, seizure disorder, or Parkinson's disease. Gender and age were also determined from the medical record.

Cognitive status was further assessed using three neuropsychological instruments. The Digit Symbol Substitution Test (DSST) measures attention and psychomotor speed. Subjects are given a code table for pairs of digits and symbols, filling the blanks with the symbol that corresponds to the digit above it, completing as many as possible in 90 seconds (Wechsler, 1981). Scores range from 0 to a theoretical maximum of 90. The DSST has been found to be more sensitive to changes in high-levels of cognition (Proust-Lima, Amieva, Dartigues, & Jacqmin-Gadda, 2007).

The Verbal Fluency scale (letters) measures word production by having subjects list as many words as possible that begin with the designated letter. Subjects have 60 seconds (Borkowski, Benton, & Spreen, 1967). Scoring is a simple count in 60 seconds.

The Word List provides a list of 9 words which are read to the subject at a rate of one word each 2 seconds. The first trial begins with a statement "I shall present a list of grocery items for you to remember. Listen carefully. When the list ends, tell me all of the items you remember. In any order." A second and third trial are also conducted, and are preceeded with 'Let's try it again." The recall score is the total number of recalled items across all 3

trials, with a possible range of 0 to 27 points. A decline of 4 points or more is considered indicative of cognitive decline (Sands, Phinney, & Katz, 2000).

The definition for (POCD) in this study is a patient who demonstrates significant decline from his/her baseline level of performance on one or more neuropsychological domains. The three cognitive tests (DSST, Verbal Fluency, and Word List) were used to assess POCD in this study and were administered preoperatively, 24 hours postoperatively, and 48 hours postoperatively. Computation using a statistical strategy for defining change (Sands, Katz, & Doyle, 1993; Sands, Katz, and Doyle, 1993, Part I; Sands, Katz, & Doyle, 1993, Part II), resulted in a definition for postoperative cognitive decline of Word List change <4, Verbal Fluency change <7, and Digit Symbol change of <7 (Wang, Sands, Vaurio, Mullen, & Leung, 2007).

Data collectors had provided the reasons for data being missing using adjectives including ‘confused,’ ‘incapable,’ ‘stuporous,’ ‘comatose,’ and ‘intubated.’ Data having these qualitative notations were re-coded as ‘incapable’ and trial scores of zero were recorded. This value of ‘0’ indicated that the patient was cognitively incapable of performing the neuropsychological test. Statistical analysis excluding the missing data (using only ‘completers’) calculated diagnoses of POCD comparing scores from baseline and Postoperative Day 1 (POD 1) and baseline and Postoperative Day 2 (POD 2). After appropriate missing trials were re-coded as ‘0’, a second set of statistical analyses were performed also comparing scores from baseline and POD 1 and baseline and POD 2. One-way analysis of variance (ANOVA) models were used to test for differences between the full data, recoded missing data, and partially completed groups. Partially completed data was data containing incomplete test trials and was scored with the partial score (not re-scored as ‘zero’).

Results

Demographic information is reflected in Table 1. Mean age of the subjects was 73.44 years and males and females each comprised approximately half of the sample. A large number of subjects had pre-existing central nervous system (CNS) disorders, most commonly previous history of delirium, history of delirium after surgery, history of dementia, history of depression, seizure disorders, or ‘other’ neurological disorders such as Parkinson’s disease. Baseline Telephone Interview for Cognitive Status (TICS) score average was 32.38 for all subjects.

Table 2 provides information regarding missing cognitive tests by postoperative day and the number that could be re-coded on both Day 1 and Day 2 using our previously described method. Missing data varied by cognitive test and postoperative day. Re-coding Word List scores from missing to zero when a patient was too cognitively impaired to complete the tests improved sample size by 13.5% of POD 1 and 12.8% on POD 2. Similarly, recoding missing data to zero for the Digit Symbol test resulted in 29.3% larger sample size on POD 1 and 22.7% on POD 2. Finally, Verbal Fluency gained 15.7% sample size with re-coding for POD 1 and 13.7% for POD 2. Re-coding of each cognitive test reduced missing data sample size to 20–32% in all cognitive tests for each day.

Table 3 provides the number of subjects who met the criteria for postoperative cognitive decline (POCD) using the original method, which excluded cases with missing data, and the number of additional subjects who met the criteria of POCD when scoring tests with our re-coding method. All three tests demonstrated increases in the percent of patients that would meet the diagnosis of POCD at both time points; however the largest change in incidence of POCD was after recoding for the Digit Symbol test.

Table 4 describes baseline predictors for missing status of neuropsychological data for the first day after surgery. Subjects with recoded missing Word List data were more likely to be older, female, have a CNS disorder, greater surgical risk, and lower TICS score. Participants with missing Digit Symbol tests were more likely to be female, with a CNS disorder, higher surgical risk and lower TICS score. These factors also held true for subjects with missing Verbal Fluency exams. On POD 2, (Table 5) subjects with missing Word List data demonstrated significant differences at the 0.05 level for all factors of age, gender, present CNS disorder, higher surgical risk, and lower TICS score. Missing Digit Symbol exams demonstrated significance only presence of CNS disorder, higher surgical risk, and lower TICS score. Lastly, Verbal Fluency tests were only significant for CNS disorder, and lower TICS score.

Discussion and Limitations

Our data suggest that using a scoring system that enters a value of '0' when patients are unable to perform cognitive testing did significantly increase the number of patients that met the diagnosis of postoperative cognitive decline using the criteria that the primary investigators had determined a priori. Excluding those values for analysis would have biased the sample toward a Type II error (failure to detect a difference). In many situations, our technique may be a preferable solution if clinical decision making and patient monitoring are affected by detecting a difference between groups, making a Type II error the more serious of the two.

Results differed by cognitive test. Not surprisingly, the Digit Symbol test was the most likely evaluation to be missing. The inability to use a pencil and paper postoperatively most likely made this test more difficult to complete than tests using verbal report. Word List was the least likely test to be missing but was more likely to be sensitive to differences in surgical factors, likely because Word List is sensitive to drug effects (Sands, Katz, & Doyle, 1993). The plan to use multiple cognitive measures is a strength of our study, however, differences in completion rates make this difficult to interpret. Likewise, re-coding created some small cell sizes which could have influenced our ANOVA and Chi-square analyses.

Our method of scoring cognitive exam scores as '0' for patients unable to perform cannot be used in all situations and may not provide an accurate measure of cognitive status when lacking more specific patient assessment data. We chose only to score data with subject information that was collected indicating a reasonable estimate that the score would be 0. Our method reduced missing data to a point that is consistent with recommended rates in traditional models of analysis, for example, from 30% down to 10% in clinical trials (Fleming, 2011). Other data suggest that missing study data of greater than 10% increases the likelihood of either Type I or Type II error (Rubin, Witkiewitz, St. Andre, & Reilly, 2007). Regular oversight and trouble-shooting meetings with all study staff can help to prevent missing data by providing suggestions to obtain follow-up scores. Likewise, previous methods of maintaining adherence to study protocols can provide examples and training methods for new data collection personnel. Given the method used here, training could include a protocol for scoring instruments when patients are unable to complete them, rather than 'refuse' to complete them. Our outcome measure was 'POCD' rather than 'delirium' we likely missed the opportunity to identify patients experiencing 'delirium' events, information which would likely be more useful clinically.

Consideration should be given regarding possible instrument burden related to missing data. Further research on the use of multiple tools and the validity of each could reduce the need to collect data at multiple time points with multiple instruments. We plan to conduct further research related to the detail of instruments to measure cognitive status. The use of one tool

may prove superior in the postoperative patient who is cognitively intact but unable to point or write (necessary for Digit Symbol completion). Similarly, finding an instrument with the best sensitivity to postoperative decline could use further study.

The use of this method depends upon accurate assessment information from original data collection that, for some studies, might not be available. In our situation, our original data collector had taken field notes and was also available for additional questions, which may not exist in other studies, particularly those with multiple research sites.

The adjustment for missing data in this study occurred retrospectively at a distant time point from original data collection. Adjustments completed at the time of data collection could adjust scores using patient ability to complete testing, or return at an agreed upon time with nursing staff that would allow for necessary postoperative care to occur along with adequate data collection.

Conclusion

Significant missing data can reduce the ability to draw conclusions and affect the interpretation of results. Previous methods to reduce missing data using imputation or 'last-measure- carried-forward' mechanisms are imprecise which may result in biased estimates of reality. In addition, previous models of data imputation depend on assumptions that cannot be verified. Clinical relevance of missing data can impact the likelihood of conclusions that are inaccurate or compromise clinical decision-making. Our method provides a preferable and meaningful mechanism for increasing the degree of usable data in longitudinal cognitive trials.

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Table 1

Demographic statistics for all subjects who had baseline tests (N = 631).

Age	73.44 ± 6.05
CNS Disorder	
0	254 (45.11)
1	309 (54.88)
Gender	
Female	307 (50.09)
Male	296 (49.09)
Surgical Risk	
0	14 (2.32)
1	469 (77.78)
2	120 (19.90)
TICS Score	32.38 ± 4.03

Age and TICS score are displayed as mean +/− SD while the rest of the variables are displayed as Count (%).

Table 2

Cognitive Test Information with Complete, Recoded, and Partially Completed Data

	Day	Cognitive Tests Complete	Recoded as '0'	Partially Completed	Not Re-coded	Total
Word List	Day 1	320 (60.0%)	72 (13.5%)	16 (3.0%)	125 (23.4%)	533
	Day 2	305 (57.2%)	68 (12.8%)	10 (18.9%)	150 (28.1%)	533
Digit Symbol	Day 1	195 (43.0%)	133 (29.3%)	4 (.9%)	122 (26.9%)	454
	Day 2	202 (44.5%)	103 (22.7%)	3 (.7%)	146 (32.2%)	454
Verbal Fluency	Day 1	305 (57.1%)	84 (15.7%)	15 (28.1%)	130 (24.3%)	534
	Day 2	299 (56.0%)	73 (13.7%)	18 (3.4%)	144 (27.0%)	534

The second column shows the number of subjects with complete cognitive decline test data, the third column the number of subjects with missing test data that could be recoded as 0, the fourth column the number of partially completed test data, and the fifth column the number of subjects with completely missing data.

Table 3

Incidence of Cognitive Decline by Test and Day

	Day	Full Data	Recoded Missing	Partially Completed
Word List		130	72	16
	One	24.4%	13.5%	3.0%
		24.4%	39.9%	42.2%
		110	68	9
	Two	20.6%	12.8%	1.7%
		20.6%	33.4%	35.1%
Digit Symbol		117	130	4
	One	25.8%	28.6%	.9%
		25.8%	54.4%	55.3%
		114	100	3
	Two	25.1%	22.0%	.7%
		25.1%	47.1%	47.8%
Verbal Fluency		114	80	12
	Day One	21.3%	15.0%	2.2%
		21.3%	36.3%	38.5%
		94	70	16
	Two	17.6%	13.1%	3.0%
		17.6%	30.7%	40.7%

Table three displays cognitive decline information by test and day. In each cell, the top number is the number of subjects diagnosed with cognitive decline, the second the percentage diagnosed with cognitive decline, and the third the cumulative percentage diagnosed with cognitive decline across rows.

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Table 4

Postoperative Day 1 (POD 1) Subject Characteristics by Test and Completion

	Variable	Full Data	Recoded Missing	Partially Completed	P-Value
Word List	Age	72.81 (5.89)	74.96 (6.69)	74 (6.70)	.02
	Gender (Female)	144 (47.5%)	46 (63.9%)	9 (60%)	.03
	CNS Disorder Yes	110 (40.1%)	66 (92.9%)	12 (80%)	<.01
	Surgical Risk				
	2	252 (83.2%)	40 (55.56%)	12 (80.0%)	<.001
	3	43 (14.19%)	31 (43.06%)	3 (20.0%)	
	TICS Score	33.21 (3.61)	30.05 (4.69)	31.78 (2.94)	<.001
Digit Symbol	Age	72.40 (5.74)	73.27 (6.08)	73.00 (6.06)	.43
	Gender (Female)	83 (45.1%)	77 (57.8%)	1 (25.0%)	.04
	CNS Disorder Yes	72 (44.4%)	101 (78.9%)	1 (25.0%)	<.01
	Surgical Risk				
	2	159 (86.4%)	89 (66.9%)	4 (100%)	<.01
	3	21 (11.4%)	41 (30.8%)	0	
	TICS Score	33.30 (3.59)	32.05 (4.41)	33.50 (2.89)	.02
Verbal Fluency	Age	72.67 (5.77)	73.79 (6.09)	73.00 (3.62)	.30
	Gender (Female)	129 (45.6%)	54 (64.3%)	8 (53.3%)	.01
	CNS Disorder Yes	107 (42.4%)	79 (95.2%)	10 (66.7%)	<.01

Variable	Full Data	Recoded Missing	Partially Completed	P-Value
Surgical Risk				
2	240 (84.8%)	52 (61.9%)	15 (100%)	<.01
3	35 (12.4%)	30 (35.7%)	0	
TICS Score	33.29 (3.29)	31.06 (4.76)	32.03 (3.90)	<.001

Postoperative day 1 descriptive statistics for age, gender, CNS disorder, surgical risk, and TICS Score stratified by test and type of data. Mean (SD) reported for age and TICS score. Frequency (%) reported for Gender, CNS Disorder, and surgical risk. ANOVA and Chi-Squared Tests of Association were used to compare the data types within each row. A small p-value is an indication of population differences between the data types.

Table 5

Postoperative Day 2 (POD 2) Subject Characteristics by Test and Evidence

	Variable	Full Data	Recoded Missing	Partially Completed	P-Value
	Age	73.2 (5.87)	75.90 (6.92)	71.3 (4.30)	.002
	Gender				
	(Female)	138 (48.2%)	39 (57.4%)	8 (80%)	.08
	CNS Disorder				
Word List	Yes	109 (43.3%)	61 (92.42%)	10 (100%)	<.001
	Surgical Risk				
	2	231 (81.1%)	46 (67.6%)	5 (50.0%)	.01
	3	50 (17.5%)	21 (30.9%)	5 (40.0%)	
	TICS Score	33.16 (2.51)	29.74 (5.58)	32.76 (2.51)	<.001
	Age	72.70 (5.76)	74.05 (6.06)	72.67 (7.51)	.17
	Gender				
	(Female)	91 (47.6%)	55 (53.3%)	2 (66.7%)	.52
	CNS Disorder				
Digit Symbol	Yes	68 (41.2%)	90 (89.1%)	2 (66.7%)	<.01
	Surgical Risk				
	2	163 (85.3%)	71 (68.9%)	3 (100%)	<.01
	3	28 (14.7%)	28 (27.2%)	0	
	TICS Score	33.40 (3.29)	31.93 (4.75)	33.33 (4.51)	.01
	Age	73.00 (5.72)	74.48 (5.71)	72.72 (5.33)	.13
	Gender				
	(Female)	129 (46.2%)	41 (56.1%)	9 (50.0%)	.31
	CNS Disorder				
Verbal Fluency	Yes	110 (44.7%)	68 (94.4%)	9 (50.0%)	<.01
	Surgical Risk				
	2	230 (82.3%)	53 (72.6%)	13 (72.2%)	.18
	3	43 (15.4%)	19 (26.0%)	5 (27.8%)	
	TICS Score	33.34 (3.12)	31.00 (5.18)	32.03 (3.95)	<.001

Postoperative day 2 descriptive statistics for age, gender, CNS disorder, surgical risk, and TICS Score stratified by test and type of data. Mean (SD) reported for age and TICS score. Frequency (%) reported for Gender, CNS Disorder, and surgical risk. ANOVA and Chi-Squared Tests of Association were used to compare the data types within each row. A small p-value is an indication of population differences between the data types.